

U.S. Application No. 10/607,719

Official
Attorney Docket No. 41740-0600**REMARKS**

Applicant respectfully requests entry of the foregoing amendments. Claims 1, 6, 9, 10, 14, 17, 19, and 20-22 have been amended. The claim amendments are fully supported by the specification. Claims 1-22 are pending in the application.

In the Official Action of September 3, 2004, claims 1-3, 5-9, 12, 13, 17 and 19 were rejected for obviousness-type double patenting over various claims of copending application Serial No. 10/324,954 in view of Chen. Claims 1-3, 6, 9, 10, 12-15 and 19 were rejected for obviousness-type double patenting over claims 1-21 of copending application Serial No. 10/324,953. Claims 1-22 were rejected under 35 USC § 112, second paragraph, as indefinite. Claims 1-22 were rejected under 35 USC § 103(a) as obvious over Laruelle in view of Chen. The specific grounds for rejection, and applicants' response thereto, are set forth in detail below.

Support for the claim amendments

The amendments to claim 1, 6, 9, 10, 14, 17, and 20-22 is supported at table 1, page 20 and page 15, lines 4-6 of the specification.

Claim rejections for obviousness-type double patenting

Claims 1-3, 5-9, 12, 13, 17 and 19 are rejected for obviousness-type double patenting over various claims of copending application Serial No. 10/324,954 in view of Chen. Claims 1-3, 6, 9, 10, 12-15 and 19 are rejected for obviousness-type double patenting over claims 1-21 of copending application Serial No. 10/324,953. Applicants respectfully traverse.

Copending application Serial No. 10/324,954 contains claims directed to formulations where a hydrophobic active ingredient is dissolved in a solubilizer such that the active ingredient forms a solution upon administration. By contrast, the present invention is directed to formulations that are self-emulsifying upon administration. Applicants respectfully submit that one of ordinary skill in the art would have no motivation to modify the compositions claimed in copending applications Serial No. 10/324,954 to arrive at the instantly claimed compositions,

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because the instant compositions are of a fundamentally different nature and intended purpose. In the absence of any motivation to make this modification no *prima facie* case of obviousness exists, and the rejection is improper and should be withdrawn.

With respect to copending application 10/324,953, applicants respectfully request that this rejection be held in abeyance until the indication of allowable subject matter in the instant application, at which time applicants will consider, if appropriate, the filing of a suitable terminal disclaimer.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-22 were rejected under 35 USC § 112, second paragraph, as indefinite. First, the Examiner alleges that the term "mono- or di- or polyethylene glycol" is unclear. Applicants believe that it is clear that "mono", "di" and "poly" are prefixes to "ethylene glycol." See also the definition at page 15, lines 4-6 of the specification. However, for the avoidance of doubt the claims have been amended to explicitly recite this. The Examiner alleges that certain language in claim 7 is unclear. However, the quoted language does not appear in claim 7 (or any other claim) and applicants therefore request withdrawal of the rejection. The Examiner next asserts that the terms C_{max} and "AUC" in claim 18 lack antecedent basis. Applicants respectfully submit that the amendment to claim 18 presented above obviates this rejection. Finally, the Examiner alleges that the range amount of surfactant in claims 20-22 is unclear. Applicants have corrected the typographical error in claims 20-22 to address this rejection and respectfully request withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-22 are rejected under 35 USC § 103(a) as obvious over Laruelle in view of Chen. Specifically, the Examiner alleges that Laruelle discloses a formulation of fenofibrate in DGME where the weight ration of DGME and fenofibrate falls within applicants' claimed range, and that Laruelle further discloses additives that aid in solubilization of the fenofibrate or

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stabilization of the formulation. The Examiner admits that Laruelle fails to disclose formulations containing surfactant or stabilizing agent, but asserts that this deficiency is remedied by Chen. The Examiner further admits that neither Laruelle nor Chen teach or suggest the amounts of ingredients recited in applicants' claims but asserts that "it is not inventive to discover the optimum or workable ranges by routine experimentation." Applicants respectfully traverse.

When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaack*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* MPEP §§ 2142-43 (August 2001). In the present case, the Examiner has failed to set forth adequate reasons as to why one of ordinary skill in the art would have been motivated to combine the cited references and therefore no *prima facie* case of obviousness exists, and the rejection should be withdrawn.

Laruelle describes compositions containing fenofibrate and DGME, but fails completely to describe a composition containing *any other* defined ingredient, let alone the ingredients specified in the instantly claimed invention. The Examiner asserts that Laruelle at column 3, lines 20-23 suggests adding additional components to increase the solubility and stability of the fenofibrate. Applicants respectfully submit, however, that the *entire* disclosure directed to solubilizers and stabilizers is the following:

According to another advantageous embodiment of the fenofibrate solution, it additionally comprises additives capable of increasing the solubilizing power of DGME and/or of increasing the stability of the said solution.

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Water-miscible glycol additives, as well as antioxidants, can be included in the proposed formula in order to substantially increase the solubilizing power of the DGME and to ensure the stability of the composition.

See column 3, lines 20-23 and column 4, lines 39-41 respectively. Nothing in Laruelle, however, would provide one of ordinary skill in the art with any further information regarding either the nature or amounts of these additives, let alone direct one to the use of a surfactant. This complete lack of disclosure leaves the person of ordinary skill in the art with no guidance whatsoever as to how to go about improving Laruelle's compositions using other solubilizers or stabilizers. Such a generalized statement amounts to no more than wishful thinking and fails both prongs of the two part test under *Vaech*. First, without any guidance as to where to look for additional ingredients, Laruelle cannot motivate one of ordinary skill in the art to combine Laruelle with a secondary reference, because of the complete lack of guidance as to what type of reference to look for. Second, in the absence of any detail regarding the nature of the additional ingredients, there cannot be a reasonable expectation of success.

The Examiner admits that Laruelle fails to disclose formulations containing surfactant or stabilizing agent, but asserts that this deficiency is remedied by Chen. Nothing in Chen, however, would provide the missing motivation to modify the compositions disclosed by Laruelle, let alone arrive at applicants' claimed compositions. In particular, Chen teaches that triglyceride is a mandatory component of the formulation and then provides huge laundry lists of possible hydrophobic ingredients¹, surfactants, stabilizers and solubilizers *etc. etc.* that *might* in some undefined situation be added to the triglyceride component in some undefined amounts to arrive at a formulation with some unspecified property.

Nothing in Chen (or Laruelle) would have motivated one of ordinary skill in the art to select fenofibrate and a surfactant to add to Laruelle's DGME in preparing a pharmaceutical formulation. Nothing in either Laruelle would have motivated one of ordinary skill in the art to prepare a self-emulsifying formulation of fenofibrate in the first place, let alone select the

¹ The list of possible hydrophobic ingredients runs over almost three columns of the patent.

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particular combination of components recited in applicants' claims. Accordingly, no *prima facie* case of obviousness exists and the rejection should be withdrawn.

Moreover, applicants respectfully query why one skilled in the art would be motivated to use a formulation such as that described by Chen, which contains triglycerides as a major component, in formulating a drug such as fenofibrate that is intended to lower serum triglyceride levels in a patient. See page 1 of applicants's specification.

In sum, there would have been no motivation to combine Laruelle and Chen and, even if such a motivation existed, nothing in the combined references would have guided one of ordinary skill in the art to applicants' claimed invention, nor provided a reasonable expectation that such a combination would be successful. Accordingly, no *prima facie* case of obviousness has been made and the rejection should be withdrawn.

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CONCLUSION

In view of the above amendment and remarks, applicants respectfully request that all objections and rejections be withdrawn and that a notice of allowance be forthcoming. The Examiner is invited to contact the undersigned attorney for applicants at 202-912-2197 for any reason related to the advancement of this case.

Respectfully submitted,

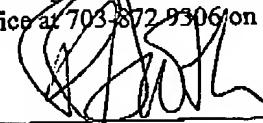
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